# Technical Data Bulletin

OH&ESD

## #174
## Respiratory Protection Against Biohazards

**Updated: March 2007**

### Introduction

Recently there has been growing interest in the use of respirators for biohazards that may be spread through the air. Diseases that may be caused by inhalation of airborne biological organisms include tuberculosis (TB), Hantavirus, anthrax, sudden acute respiratory syndrome (SARS) and now Avian Flu (H5N1). Biohazards may become airborne; perhaps as the agent itself such as an anthrax spore, or riding on some other material that becomes airborne such as dusts, mists or droplet nuclei. Hantavirus infection has been caused by people inhaling soil that became airborne after rodents shed virus via urine, feces or other materials into the soil. In fact, it is generally thought that airborne viruses are normally attached to other particles and rarely exist as naked organisms.[1]

Inhalation of these bioaerosols may be reduced by wearing respirators. The Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO) and many National Health Authorities have made numerous recommendations for respirator use where they believed the potential for the spread of disease by the airborne route exists. Recommendations for respiratory protection have also been made for workers involved in culling and inspecting infected birds, and for people exposed to sick birds. Issues with using respirators for exposure to bioaerosols include filtration, microorganism survival on the filter, reaerosolization of the bioaerosol, reuse of the respirator, fit and the level of exposure reduction provided by the respirator. These topics are addressed in this bulletin.

### Routes of Exposure

Inhalation is not the only route of exposure for biohazards. Infection may occur from other routes of exposure such as ingestion, skin and mucous membrane penetration (including the eyes) and animal and insect bites. Skin and mucous membrane penetration may occur by direct contact with aerosols or secondarily; e.g., a hand touching a contaminated surface and then touching a mucous membrane.

### Controls

How the disease is spread indicates what types of controls are useful in preventing its spread. If the disease can be spread by contact, preventing surfaces from becoming contaminated and hand hygiene will be very important. Surgical masks may be worn by infected people in order to reduce the spread via exhaled aerosols. Surgical masks, safety glasses and face shields may be used to shield the healthcare worker's mucous membranes (eyes, nose, and mouth). Use of respirators may also be appropriate.

It is believed that most cases of Avian Influenza (H5N1) in humans have resulted from contact with infected poultry or contaminated surfaces.[2] In such situations, people should avoid contact with infected birds or contaminated surfaces, and should be careful when handling and cooking poultry. Strict hand hygiene must also be performed. In addition to direct contact with infected poultry or contaminated surfaces, it is possible that the particles that contain Avian Flu virus could become airborne. When airborne, this virus like other biological agents can be filtered by respirators with particulate filters. Because no respirator will prevent the inhalation of all particles, they cannot eliminate the risk of exposure, infection and illness. With so many respirator use recommendations being made on websites and other sources, it is important to understand respirators and the role they have.

### Terminology

**Bioaerosols** are those airborne particles that are living or originate from living organisms.[3] They include microorganisms and fragments,

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toxins and particulate waste from all varieties of living things.

A **respirator** is a device designed to help provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.[4] For bioaerosols, particulate removing respirators are often recommended to help reduce exposure. Particulate respirators are available as:

1. a filtering half facepiece respirator where the filter is the entire respirator
2. an elastomeric half mask + particulate filter
3. an elastomeric full facemask + particulate filter
4. a powered air purifying respirator (PAPR) that includes a particulate filter

Particulate respirators are classified by their performance against local certification standards. In the US, testing is done by the National Institute for Occupational Safety and Health (NIOSH). In Europe respirators are tested against the relevant European Standard and are approved as category 3 devices under the PPE Directive 89/686/EEC. Filtration efficiency is one of the tests used for certification. These tests are designed to be very stringent or "worst case." Following are some of the minimum filtration requirements according to US and European standards. However, it is often inappropriate to compare results from the different tests as there are many protocol factors that affect performance such as type of aerosol, particle size, flow rate, whether the aerosol has been charge-neutralized to the Boltzmann equilibrium state, etc.

It should be noted that penetration of particles through the filter is only one of the possible sources of exposure to contaminants. Other potential sources such as face seal leakage, improper maintenance, or not wearing the respirator when necessary may contribute more to exposure than filter penetration. Each of these must be addressed and controlled. For example, all particulate respirators designed to seal to the face (including filtering facepiece respirators) can be fit tested using the saccharin or Bitrex™ qualitative fit test methods. Wearers must be trained how to properly maintain their respirators and the importance of wearing them all of the time during potential exposure.

It should also be noted that respirators only reduce exposure. In many countries, types or classes of respirators are given an "assigned protection factor" or APF. APF is the expected ability of the respirator to reduce exposure when used according to an effective respiratory protection program. For example, an APF of 10 means that a respirator may reduce exposure by a factor of 10 (or 90%) when properly selected, maintained, fitted and worn. Therefore, even if a filter is 100% efficient, the expected amount of exposure reduction would be limited by the APF. Because no respirator will prevent the inhalation of all particles, they cannot eliminate the risk of exposure, infection and illness.

For more information on the proper selection and use of respiratory protection, please see the US OSHA standard for respiratory protection (29 CFR 1910.134), EN 529 Respiratory protective devices Recommendations for selection,

| Standard | Classification | Filter Efficiency |
|---|---|---|
| NIOSH 42 CFR 84 | 95 | ≥ 95% |
| NIOSH 42 CFR 84 | 99 | ≥ 99% |
| NIOSH 42 CFR 84 | 100 | ≥ 99.97% |
| EN149:2001 | FFP1 (filtering facepiece) | ≥ 80% |
| EN149:2001 | FFP2 (filtering facepiece) | ≥ 94% |
| EN149:2001 | FFP3 (filtering facepiece) | ≥ 98% |
| EN143:2000 EN140:1999, EN136:1998 | P1 (elastomeric facepiece) | ≥ 80% |
| EN143:2000 EN140:1999, EN136:1998 | P2 (elastomeric facepiece) | ≥ 94% |
| EN143:2000 EN140:1999, EN136:1998 | P3 (elastomeric facepiece) | ≥ 99.95% |

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use, care and maintenance — Guidance document[5] or any applicable local standards.

A **surgical mask** is an infection control device designed to help prevent the spread of infection from the wearer's exhaled breath to potentially susceptible persons.[6] A surgical mask may help reduce contamination of the environment by filtering large droplets expelled by the wearer. However, since surgical masks are not tested the same as respirators any "filtration efficiency" claims can not be directly compared to those for a respirator. A surgical mask may also be tested to for its ability to reduce exposure of the wearer against fluid splashes. Most surgical masks are not designed to seal tightly to the face.

In a few cases, an approved respirator may also have the attributes of a surgical mask. This means it can help filter large droplets expelled by the wearer, but has also been shown to have efficacy at filtering smaller particles, and is designed to fit tightly to the face. Because of its additional use as a respirator, this type of surgical mask must also be fit tested.

**Filtration**

A number of questions have been raised regarding the use of respirators against biological agents. The primary question is whether or not particulate respirators can filter small particles such as fungal spores (2 to 5µm), bacteria (0.3 to 10µm), or viruses (0.02 to 0.3µm).[7] The physical size of various organisms is shown in Table 1. As noted previously, biological organisms may be carried on other particles including dust, blood, saliva, etc. Droplets generated from talking, coughing or sneezing will quickly dry in the air to form droplet nuclei. Droplet nuclei generated from a sneeze are thought to be nominally between 0.5 to 12µm.[7] It is thought that droplet nuclei that may contain *mycobacterium tuberculosis* are 1-5µm[8] although others have included droplet nuclei less than 0.65µm.[9] Understanding filtration mechanisms can help answer whether or not these particles can be filtered by particulate respirators.

Many particulate respirators use a non-woven fibrous filter media to capture particles. Fibers from less than 1µm to 100µm in size crisscross to form a web of many layers which is mostly air. It is the spaces between fibers that allow for breathability. Therefore, a particle does not become trapped because it tries to go through a hole that is too small. Rather, while "trying" to navigate through the layers of filter media, a particle becomes attached to a fiber due to a number of different mechanisms. The most common of these are gravitational settling, inertial impaction, interception, diffusion, and electrostatic attraction.[1]

To understand how a particle is captured, one must first consider the movement of air through the filter media. The path of the air around a fiber may be described in terms of imaginary streamlines. Any particle carried by the air may or may not stay within the streamlines depending largely upon the particle's size (aerodynamic diameter).

Very large particles in slow moving airstreams may settle out due to gravity. However, most respirable particles are too small for this mechanism. Respirable particles above 0.6µm in diameter may be captured by interception and inertial impaction.[10] Inertial impaction occurs when a particle cannot follow a streamline around a fiber because of its inertia and instead impacts into the fiber. In the interception mechanism, the particle holds to the streamline, but that streamline will naturally bring the particle close enough to come in contact with the fiber. In contrast, diffusion mainly affects particles under 0.1 µm. Random movements of air molecules collide with these very small particles and cause them to wander across streamlines until they come in contact with a fiber.

Because of the complex methods by which particulate filtration occurs, the smallest particles are not always the most difficult to filter. Most particulate filters have a region of minimum filtration efficiency somewhere between 0.05-0.5µm.[1] Particles in this range are large enough to be less effectively pushed around by diffusion, but small enough to be less effectively captured by interception or impaction. The most penetrating particle size (MPPS) will depend on the filter media, air flow, and electrostatic charge on the particle. Filters that use

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electrostatic attraction may have a MPPS shifted to a slightly smaller size range.

Filtration efficiencies of six different commercially available US N95 filtering facepiece respirators as tested by 3M are shown in the left side of Figure 1. (Previous research has shown that for 3M products, European FFP2 respirators have equivalent or better filtration efficiency in tests representative of health care environments.) Averaged filtration efficiencies are shown as a function of different sized sodium chloride particles at a flow rate of 85 liters per minute.

While there was variability between different samples of the same model respirator, and between different models, the MPPS included particles with a diameter between 0.04 and 0.1µm. As seen in Figure 1, particles that are smaller or larger than the MPPS are captured with higher filtration efficiency. Filtration via diffusion (most noticeable for particles smaller than 0.1µm) actually increases as particle size decreases. Other research has confirmed that filter efficiency increases with decreasing particle size, even for particles as small as 0.003µm (much smaller than that of virus).[11]

A size distribution from a sneeze is shown on the right side of Figure 1.[12] It should be noted that most of the droplet nuclei are larger than the MPPS. In other words, droplet nuclei that may contain microorganisms will be filtered by these respirators with high efficiency.

There has been much confusion regarding the MPPS. Some of this may be due to the different methods used to describe the size of particulate aerosols. For bioaerosols, microbiologists may cite the size of the physical organism as shown in Table 1. Industrial hygienists often use the shape and density of the particle to calculate an aerodynamic diameter. The aerodynamic diameter is used to estimate how a particle travels through air or is deposited in the human respiratory tract. Filtration research with smaller particles is often done using a device which selects different sized particles according to the particle's ability to move through an electric field while falling. This size is called a mobility diameter.

Another possible source of confusion is the statistical terms used to describe aerosols in respirator test methods. Respirators are tested against aerosols that contain a range of different sized particles. For example, in the US, the median size of the sodium chloride aerosol is 0.075µm. However, if the same aerosol was characterized by mass instead of by count, the mass median aerodynamic diameter would be approximately 0.3µm. Therefore, care needs to be taken when comparing filtration claims. To be safe, make sure to use a respirator that has been tested and approved per all applicable local regulations. And, as mentioned above, filtration efficiency is just one of the required components that needs to be considered when selecting and using a respirator.

An often-expressed question is whether biological aerosols are removed by respirator filters the same as non-biological aerosols. Due to concerns on the efficacy of respirator filters for *Mycobacterium tuberculosis* (TB), many studies were conducted using bioaerosols. These filter evaluations were conducted over a range of test conditions (flow, humidity), biological species representing various shapes (spheres, rod, and rod/sphere shape) and sizes, filter performance levels and varying filter media (mechanical and electret; polypropylene and fiberglass). These experiments[13-17] published in peer reviewed literature have demonstrated that there is no significant difference in the filtration of biological aerosols and non-biological aerosols. Spherical particles were usually more penetrating than rod-shaped particles with equivalent aerodynamic diameter over a range of particle sizes. A more recent study confirmed that nonbiological particle simulants (sodium chloride–NaCl) can be used for assessing the performance of respirators against virons.[18]

### Microorganism Survival on Filters

Another area of focus is about the survival of microorganisms on respirator filters. This could impact storage and handling procedures. Again several studies have been conducted regarding survival on

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filters. Over 18 types of respirator filters and five surgical masks have been studied using several types of microorganisms followed by storage at various humidities.[19-23] The filters were typically loaded with the microorganisms at experimental concentrations that were probably higher than those expected in work settings.

The polypropylene filters used in these studies were then checked for survival of microorganisms ranging from immediately after loading to as many as 28 days later, depending on the experiment. These studies have demonstrated that there were surviving organisms immediately after loading and that they survived for varying lengths of time depending on the storage conditions of the study. Usually storage under high humidity conditions was the most favorable for long term survival. However, these storage conditions are not typical of respirator storage in respirator programs. Storage of filtering facepieces used against bioaerosols in resealable plastic bags may not be appropriate. The filters may be moist from use and storage in plastic will keep the humidity level high. These studies also indicate that while the microorganisms can remain viable on the filter, they were unable to grow.

One of these studies looked for migration of the organism to the inside of the filtering facepiece respirator and concluded that respirators may be reused over time with little risk even after a week's time of internal contamination provided the respirator is carefully handled and stored (handled by non-filter components, e.g., straps).[23] The investigators felt any internal contamination from environmental bacteria was due to handling (removal from bag to sample).

One study looked at two high efficiency filters with varying percentages of cellulose.[22] These filters were inoculated with *Stachybotrys atra* and stored at RH as high as 100% for 86 days. *S. atra* grew and produced toxins on these cellulose filters at the high RH conditions. Again these conditions are not typical during normal respirator use and storage.

These concerns have prompted some to state that a traditional filter without a nanoparticle coating of a biocide would turn into a breeding ground for a virus or bacterial agent. The studies mentioned above do not support this claim. While it may be relatively easy to load a filter with a biocide, determining its efficacy is more difficult. Close examination of the claim needs to be made. Claims often relate to protection of the product, such as from microbial decay rather than protection of the wearer. In many countries, in order to claim biocidal effectiveness for protecting the wearer, the product must be in compliance with local regulations. In the US, claims are regulated by the Environmental Protection Agency (EPA). In Europe, claims must be in compliance with the Biocide Product Directive (98/8/EC). If the claims have not been approved or are not in compliance, they may be inappropriate. Having the filter treated may only extend the shelf life of the filter. While most of the virus would be deposited on the filter as a result of breathing through the filter, bioaerosol will also be deposited on the straps, exhalation valve cover (if present), and nose clips etc. Thus caution in handling the respirator must still be taken and a biocide filter treatment may not prevent the spread of disease by contact.

Overall, these studies suggest careful consideration for filter handling, reuse and respirator disposal, especially where the organism can be spread by contact. Precautionary measures might include the use of gloves and washing hands after handling the respirator. For organisms transmitted only by inhalation, respirator handling may not be critical. One investigator suggested training for respirator users might be necessary to recognize when exposures would require immediate disposal of respirators.

### Reaerosolization of Microorganisms

Once a particle is collected onto a fiber, it will adhere to the filter fiber due to Van der Waals forces. Therefore, filters are likely to be good collectors of small particles. In contrast, reaersolization is the process by which any aerially deposited material on the filter can be re-suspended. It could be hypothesized to happen if there was high air flow back through

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the filter such as if the wearer were to cough or sneeze while wearing the respirator. One experiment used three microorganisms and two surrogate particles [NaCl and Polystyrene latex (PSL) particles] of various size ranges from 0.6 µm to 5.10µm.[24] They were loaded onto three models of filtering facepiece particulate respirators. The reentrainment velocity was 300cm/sec. Reaerosolization was significant only for larger test particles (3 and 5µm) into dry air. There was no reaerosolization when the RH levels were greater than 35%. These authors concluded that reaerosolization of collected TB bacteria and other particles less than a few microns in size is insignificant at conditions encountered in respirator wear. They also speculated that the conclusions were valid for other fibrous filters as well.

In a second study, investigators used 1µm PSL particles to simulate anthrax spores.[25] The two models of filtering facepiece particulate respirators were loaded with ~20 million particles. The respirators were then dropped three feet onto a hard surface. The amount released ranged from 0 to 0.5% and the average release measured 0.16% and 0.29% for the 2 models. While this loading represents a much higher degree of loading than would be expected in typical work environments, this study indicates a small, but consistent fraction of 1µm particles captured by a respirator filter may be released into the air. These results suggest caution in handling and disposing of respirators contaminated with anthrax spores.

**Selection and Use**

When respiratory protection is needed against bioaerosols, the user should select a certified / approved particulate respirator according to recommendations from CDC, WHO or applicable local regulations. Remember that the NIOSH particulate filter rating does not include face seal leakage, only filter penetration. Therefore, the assigned protection factor must be considered to ensure the expected reduction in respirator exposure is adequate for your intended application. Although the European certification testing includes face seal leakage, some countries have assigned protection factors that are lower than nominal protection factors calculated from the certification tests.

Once a respirator has been selected, a continuing, effective respiratory protection program as specified by applicable local regulations must be implemented. This includes training on the respiratory hazards, fit testing, maintenance, disposal, etc.

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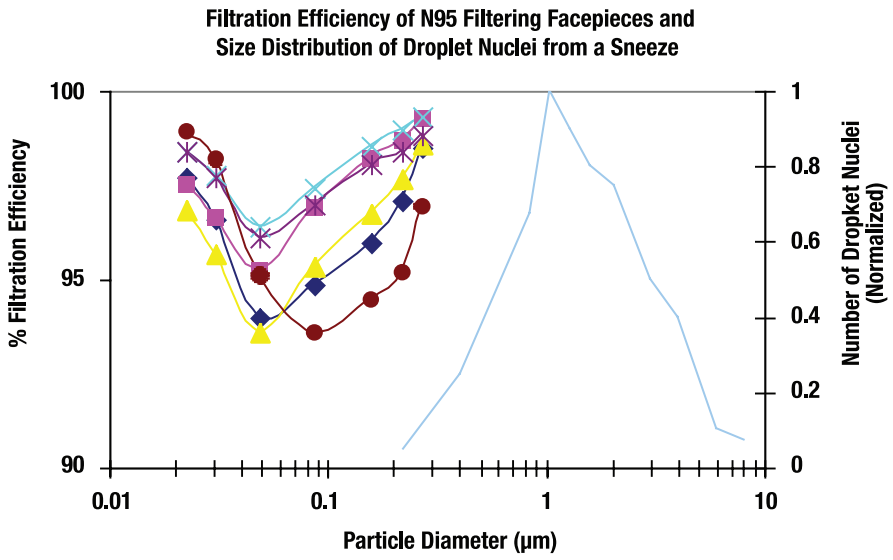
**Table 1. Size of Various Microorganisms**

| Microorganism (common name or disease) | Physical Size (µm) |
|---|---|
| Hepatitis virus (Hepatitis B) | 0.042 – 0.047 |
| Adenovirus (respiratory infections) | 0.07 – 0.09 |
| Filoviruses (Ebola) | 0.08 diameter<br>0.79-0.97 length |
| Bunyaviridae (Hantavirus) | 0.08 – 0.12 |
| Orthomyxoviridae (Influenza A, B, & C) | 0.08 – 0.12 |
| Coronaviridae (SARS –CoV) | 0.10 – 0.12 |
| Variola Virus (Smallpox) | 0.14 – 0.26 diameter |
| 0.22-0.45 length | |
| *Mycobaterium tuberculosis* (TB) | Droplet nuclei that contain the organism often cited as 1 – 5 µm diameter, but may be smaller |
| *Bacillus anthracis* spore (Anthrax infection) | 1.0 – 1.5 diameter |

**Figure 1. Averaged Filtration Efficiency for Six N95 respirators (on the left), and Size Distribution of Droplet Nuclei from a Sneeze (on the right).**

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